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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,753	10/30/2001	Ken Fujise	UTSH:251US	6306
7590 03/26/2004			EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. A REGISTERED LIMITED LIABILITY PARTNERSHIP SUITE 2400 600 CONGRESS AVENUE AUSTIN, TX 78701			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 03/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/021,753	<b>Applicant(s)</b> FUJISE ET AL.	
	<b>Examiner</b> J. Eric Angell	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

Claim 1-62 are pending and addressed herein.

#### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, and 16-19, drawn to a method of inhibiting a hyperproliferative cancer cell, including treating cancer, by providing an inhibitor that reduces the amount of Fortilin in the cancer cell, classified in class 514, subclass 1, for example.

Should Group I be elected further Group election of one of the following subgroups (A-D) must also be made. To be clear, the following subgroups are not species -- they are independent and distinct subgroups of Invention I.

- A. Claim 5, drawn to the method of Group I wherein the inhibitor reduces Fortilin activity by reducing its binding to p53. Class 514, subclass 1, for example.
- B. Claim 6, drawn to the method of Group I wherein the inhibitor reduces Fortilin activity by reducing its binding to MCL1. Class 514, subclass 1, for example.
- C. Claims 7 and 8, drawn to the method of Group I wherein the inhibitor decreases the amount of Fortilin in the cell by decreasing the expression of Fortilin. Class 514, subclass 44, for example.

Should Subgroup C. be elected further Group election of one of the following subgroups (i or ii) must be made. To be clear, the following subgroups are not species -- they are independent and distinct subgroups of Invention C.

- i. Claim 9, drawn to the method of Group C wherein the inhibitor decreases transcription of Fortilin. Class 514, subclass 2, for example.
- ii. Claim 10, 13-15 and 21-28, drawn to the method of Group C wherein the inhibitor decreases translation of Fortilin and wherein the inhibitor is a nucleic acid expressed in antisense orientation. Class 514, subclass 44, for example.

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D. Claims 11 and 12, drawn to the method of Group I wherein the inhibitor is an antibody specifically binds Fortilin. Class 424, Subclass 130.1

II. Claims 1, 4, 16, 17 and 20 drawn to a method of inhibiting a hyperproliferative vascular cell, including treating atherosclerosis, by providing an inhibitor that reduces the amount of Fortilin in the vascular cell, classified in class 514, subclass 1, for example.

Should Group II be elected further Group election of one of the following subgroups (A-D) must also be made. To be clear, the following subgroups are not species -- they are independent and distinct subgroups of Invention II.

A. Claim 5, drawn to the method of Group II wherein the inhibitor reduces Fortilin activity by reducing its binding to p53. Class 514, subclass 1, for example.

B. Claim 6, drawn to the method of Group II wherein the inhibitor reduces Fortilin activity by reducing its binding to MCL1. Class 514, subclass 1, for example.

C. Claims 7 and 8, drawn to the method of Group II wherein the inhibitor decreases the amount of Fortilin in the cell by decreasing the expression of Fortilin. Class 514, subclass 44, for example.

Should Subgroup C. be elected further Group election of one of the following subgroups (i or ii) must be made. To be clear, the following subgroups are not species -- they are independent and distinct subgroups of Invention C.

i. Claim 9, drawn to the method of Group C wherein the inhibitor decreases transcription of Fortilin. Class 514, subclass 2, for example.

ii. Claim 10, 13-15 and 21-28 drawn to the method of Group C wherein the inhibitor decreases translation of Fortilin and wherein the inhibitor is a nucleic acid expressed in antisense orientation. Class 514, subclass 44, for example.

D. Claims 11 and 12, drawn to the method of Group II wherein the inhibitor is an antibody specifically binds Fortilin. Class 424, Subclass 130.1

- III. Claims 29-32, drawn to a method of treating cancer comprising administering a Fortilin modulator and a second anti-cancer treatment, classified in class 514, subclass 1, for example.
- IV. Claims 33 and 34, drawn to a method for inhibiting apoptosis in a cell comprising administering a Fortilin polypeptide to the cell, classified in class 514, subclass 2.
- V. Claims 35-38, drawn to a method for inhibiting apoptosis in a cell comprising administering an expression cassette that expresses Fortilin polypeptide to the cell, classified in class 514, subclass 44. Note: claim 33 and 34 are improper linking claims. As such if Group V is elected claim 33 must be amended such that it is directed to administering a nucleic acid encoding and expressing Fortilin polypeptide.
- VI. Claims 39-47, drawn to a method for identifying a modulator of Fortilin polypeptide, classified in class 435, subclass 6.
- VII. Claims 48-52 and 54-56, drawn to a method for diagnosing cancer, classified in class 435, subclass 6. NOTE: it is believed claims 54-55 should depend on claim 53, not claim 52, if claims 54-56 are amended to depend on claim 53, they will be re-grouped with Group VIII.
- VIII. Claim 53, drawn to a method of preventing apoptosis in a cell comprising administering Fortilin polypeptide to the cell, classified in class 514, subclass 2.
- IX. Claims 57-59, drawn to a method of preventing apoptosis in a cell comprising administering a nucleic acid encoding Fortilin polypeptide to the cell, classified in

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class 514, subclass 2. Note: claim 53 is an improper linking claim. As such if Group VIII is elected claim 53 must be amended such that it is directed to administering a nucleic acid encoding and expressing Fortilin polypeptide.

- X. Claim 60, drawn to a method of treating a patient with a spinal cord injury by administering Fortilin, classified in class 514, subclass 2, for example.
- XI. Claim 61, drawn to a method for preventing muscle atrophy by administering Fortilin, classified in class 514, subclass 2, for example.
- XII. Claim 62, drawn to a method for treating myocarditis or acute myocardial infarction by administering Fortilin to a myocyte cell in the subject, classified in class 514, subclass 2.

2. Claims 1, 16, 17 links Invention I and II; claims 2 and 3 link Inventions I:A-D; claims 2, 3, 7 and 8 link Inventions I:C:i and ii; claims 4 and 20 link Invention II:A-D; claims 4, 7, 8 and 20 link inventions II:C:i and ii. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Please note that linking claims are claims that are listed in multiple Groups (other than those explicitly indicated as non-linking claims). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional

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statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-XII (as well as subgroups I: A-D, i and ii; and subgroups II: A-D, i and ii) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation, different functions and different effects. For instance, methods of inhibiting proliferation of a vascular cell are independent and distinct from methods of inhibiting proliferation of a cancer cell because cancer cells are immortalized cells and vascular cells (such as atherosclerosis) cells are not immortalized and as such, inhibiting the proliferation of one cell type would not be indicative that the method could be used to reduce proliferation of the other cell type. Furthermore, the different Groups and subgroups utilize different materials which have different modes of operation and different effects. For instance, inhibitors of transcription are different from inhibitors of translation, as are antibodies. Additionally, a Fortilin modulator is different than a Fortilin inhibitor or activator because a modulator must be able to increase and decrease Fortilin activity, thus it has different functions and effects. Also, methods reducing Fortilin is different from methods of increasing Fortilin; and methods of identifying a modulator of Fortilin, methods of diagnosing cancer, methods of preventing apoptosis, treating spinal cord injury, preventing muscle atrophy and

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treating myocarditis or acute myocardial infarction are different and encompass methods with different method steps, different materials and have different functions and effects. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

The species of cancer cells are listed in claims 3, 19. Election of a single species of cancer cell is required, if a group encompassing claims 3 and 19 is elected.

The species of viral vectors are listed in claim 23. Election of a single species of viral vector is required, if a Group encompassing claim 23 is elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (one of each Group, if necessary) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the



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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.  
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DAVE T. NGUYEN  
PRIMARY EXAMINER